DOLPHIN® 3
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, MA 01772

JUL 19 2011

510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
DOLPHIN® 3 Fluid Management System

General Information

Manufacturer/Submitter:	Gyrus ACMI, Inc 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Graham A. L. Baillie MS Associate Manager, Regulatory Affairs
Date Prepared:	March 25, 2011

Device Description

Classification Name:	Hysteroscopic Insufflator Class 2 21 CFR 884.1700 85 HIG
Project Name:	DOLPHIN® 3
Trade Name(s):	DOLPHIN® 3 Fluid Management System
Generic/Common Name:	Hysteroscopic Insufflator

Predicate Devices

Gyrus ACMI DOLPHIN® II Fluid Management System

Intended Use

The DOLPHIN® 3 Fluid Management System provides low viscosity liquid distension of the uterus for hysteroscopy, and monitors intrauterine pressure, fluid use and fluid deficit.

Product Description

The DOLPHIN® 3 will be used during Hysteroscopic procedures where physicians need to monitor fluid pressure and fluid loss. The system will provide delivery of low viscosity distension fluid through a disposable tubing set that includes an integrated pressure transducer. The system will calculate and display fluid pressure and fluid deficit while providing distension of the uterus for visualization and flow. The

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DOLPHIN® 3 provides both audible and visual alarms if pressure levels are too high or if the user-set fluid deficit alarm levels are exceeded.

The DOLPHIN® 3 incorporates a two-bag distension fluid system that utilizes a bladder bag to provide steady pressure on (each) the fluid bags. The two bladder bags are essentially pneumatic "bag squeezers" set within a rigid housing that contains the fluid bags. The DOLPHIN® 3 fluid pump adjusts the pressure applied to the distension fluid bags by inflating or deflating the pneumatic bladder. The infusion pressure can be set by the user between 40-140 mm Hg (40 mmHg is the factory default setting at power up) The system can accommodate 1, 2 or 3 liter fluid bags. The sterile/disposable tubing set with integrated pressure transducer is used to deliver fluid from the DOLPHIN® 3 to the inflow port on the hysteroscope. The device weighs the fluid in order to calculate the deficit. Any fluid dispensed but not returned to the collection canisters is considered part of the deficit.

Summary Listing of Nonclinical/Bench Testing

The following performance/functional tests were conducted to verify that the subject device met specified requirements.

1) **Pressure Accuracy vs Flow Rate**: Illustrated the intrauterine pressure developed by the DOLPHIN®3 at various output pressures and flow rates. Comparitive testing included three different make/models of hysteroscopes. The intrauterine pressure versus flow data for the predicate and subject devices were plotted for each scope.

2) **Simulated Procedure**: Verify that fluid management data accuracy and alarm functions are maintained throughout a simulated procedure.

3) **Load Cell Overstrain Test:** Verify functionality of the mechanical Load Cell protection incorporated in the design of the DOLPHIN®3 Load cell sub assemblies (upper and lower) by applying an overstraining force on the load cells.

4) **Fluid Bag and Canister Compatibility Test**: The purpose of the test was to verify the equipment is compatible and functions with the recommended manufacturer's fluid bags of various sizes and recommended collection canisters.

5) **Calibration Protocol**: Verified functionality of the Calibration module and Calibration Verification module. Checked accuracy through the working range of all the load cells in the machine and verified the functionality of the software trigger for Passing/Failing the calibration check.

6) **External Transducer Check Test**. The purpose of the test was to determine the ability of the subject device to identify faulty external pressure transducers (part of the Tubing Set) due to open wiring connections.

7) **Internal Pressure Transducer Check Procedure:** Verify the software and hardware pressure cutout limits meet performance specifications.

8) **Acoustic Level Test**: In all cases alarms were measurably discernible from the pump background noise and audible to the operator.

9) **Bladder Bag Inflate/Deflate Test:** The purpose of the test was to verify PPS requirements for Bladder Bag inflate/deflate times and flow rates.

10) **Operational Tilt Test**: Determined the subject device's ability to operate and maintain fluid deficit accuracy, when subjected to an incline and tilt deviation from a normal operational position on a level floor.

11) **Dolphin 3 Splash Test**: This test verified that the DOLPHIN®3 Hysteroscopic Fluid Management System will function within the Product Performance Specifications immediately after being subjected to an in-process splash of conductive solution and also function after allowing a 24 hour drying period to occur
12) **Pneumatic Test Protocol**: The purpose of the test was to verify pump and pneumatic circuit performance requirements.
13) **Operational Environment Test**: Verify (1) the subject device operates within its intended operating environment as specified in product performance specifications and (2) that the device continues to operate after exposure to vibration/shock likely to be experienced during use. Proper Dolphin operation was verified by completing the following functional tests:

- LCD and LED Initialization Tests
- Alarms Initialization Test
- Calibration Functional Test
- Fluid Test
- Inspection for Visible Damage

14) **Pressure vs. Bag Volume**: This test characterizes the ability of DOLPHIN®3 to maintain pressure as the irrigation bag drains.

The following standards were referenced in electrical safety, EMC, biocompatibility and sterilization testing:

1) **IEC 60601-1**, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
2) **EC 60601-1-2**, Medical electrical equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests Edition 2.1(Edition 2:2001 consolidated with Amendment 1:2004)
3) **AAMI / ANSI / ISO 10993-1**, Biological evaluation of medical devices -- Part 1: Evaluation and testing (2003)
4) **AAMI / ANSI / ISO 10993-5**, Biological evaluation of medical devices – Part 5 : Tests for In Vitro Cytoxicity (1999)
5) **AAMI / ANSI / ISO 10993-7**, Biological evaluation of medical devices – Part 7: Ehylene Oxide Sterilization Residuals. (2001)
6) **AAMI / ANSI / ISO 10993-10**, Biological evaluation of medical devices – Part 10: Tests for Irritation and Delayed-type (2002)
7) **AAMI /ANSI / ISO 11135-1**, Sterilization of health care products – Ethylene oxide – Part1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
8) **AAMI /ANSI / ISO 11607-1**, Packaging for terminally sterilized medical devices – Part1: Requirements for materials, sterile barriersystems and packaging systems, 3ed (2006)
9) **AAMI /ANSI / ISO 11607-2,** Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly process, 1ed (2006)

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Technological Characteristics and Substantial Equivalence

The DOLPHIN® 3 Hysteroscopic Insufflator is an upgrade to the predicate DOLPHIN® II device currently marketed by Gyrus ACMI, Inc. The DOLPHIN® 3 will be marketed with updated software, hardware, and an additional fluid distension bag. The DOLPHIN® 3 will have the identical indications as the predicate DOLPHIN® II, K011876. The software, mechanical design and tubing set have been updated to accommodate the additional fluid bag. The same bladder bag and self contained pump design, used in the DOLPHIN® II to regulate fluid pressure, is incorporated in the DOLPHIN® 3. The tubing set and integrated transducer remains a single use accessory sterilized by EtO.

In summary, the DOLPHIN® 3 is substantially equivalent to the predicate DOLPHIN® II device and presents no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Graham Baillie
Associate Manager, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Road
SOUTHBOROUGH MA 01772

JUL 19 2011

Re: K110852
Trade Name: DOLPHIN®3 Fluid Management System
Regulation Number: 21 CFR §884.1700
Regulation Name: Hysteroscopic insufflator
Regulatory Class: II
Product Code: HIG
Dated: June 23, 2011
Received: June 24, 2011

Dear Mr. Baillie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110852

Device Name: DOLPHIN® 3 Fluid Management System

Indications For Use:

The DOLPHIN® 3 Fluid Management System provides low viscosity liquid distension of the uterus for hysteroscopy, and monitors intrauterine pressure, fluid use and fluid deficit.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110852